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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,077	11/22/2005	Ulrich J. Pfeiffer	PFEIFFER ET AL -4 PCT	2638

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ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,077	PFEIFFER ET AL.	
	Examiner	Art Unit	
	Quynh-Nhu H. Vu	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/22/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "**the further catheter lumen (6) is open in the region of the catheter tip**" in claim 12; and "**the further catheter lumen (6) is closed in the region of the catheter tip**" in claim 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

Claim 9 s objected to because of the following informalities: claim 9 should be depended on claim 7 instead of claim 6. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 3, 5-6 and 12-15 rejected under 35 U.S.C. 102(b) as being anticipated by Lieber et al. (hereinafter 'Lieber') (US 5,66,620).

Regarding claims 1, 3, 5-6 and 14-15, Lieber discloses, in fig. 6 a catheter 10 having a catheter body 12, the interior of which form a first catheter lumen 36 which serves to accommodate a guide wire, having at least one partition disposed in the interior, which divides of at least one further catheter lumen 40 in the interior, wherein the catheter body 12 has a tubular outer wall and the cross-sectional area of further catheter lumen 40 is smaller than the cross-sectional area of the first catheter lumen 36, and the further catheter lumen 40 is disposed in such a manner that it has a wall section that is part of the tubular outer wall. The partition runs in arc shape (claim 3); the cross-sectional area of the first catheter lumen 36 has part of rounded sickle shape (claim 5);

sectional area of the first catheter lumen 36 has part of rounded sickle shape (claim 5); the cross-sectional area of the further catheter lumen 40 is round (claim 6). Catheter body 12 is made of polyurethane material (col. 5, lines 13-19) (claims 14-15).

Regarding claim 2, the cross-sectional area of the first catheter lumen F36~ 0.0024 in2, the width / diameter of the first catheter lumen D36 ~ 0.056 inches; the cross-sectional area of the further catheter lumen F40 ~ 0.0016 in2, the width of the further catheter lumen D40 range from 0.01 inches to 0.024 inches (col. 5, lines 20-35). From here, we can enter data in to equation below:

(F36/F40) > (D36/D40)^2

(F36/F40) = (0.0024)/(0.0016) = 15 in2

(D36/D40)^2 = (0.056/(0.01 to 0.024)) ^2 = 5.444 to 31.36 in^2

Therefore, it meets the limitation of the equation above.

Regarding claim 12, at least one catheter lumen is open in the region of the catheter tip (inherently).

Regarding claim 13, one catheter lumen is closed in the region of the catheter tip (Fig. 6, col. 7, lines 15-17).

Claims 1, 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Beil (US 6,146,354).

Beil discloses, in Fig. 3, a catheter 26 having a catheter body, the interior of which forms a first catheter lumen 28, which serves to accommodate a guide wire during the introduction of the catheter into the body of a patient (col. 2, lines 10-17),

further catheter lumen 30 in the interior, wherein the catheter body has a tubular outer wall and the cross-sectional area of the further catheter lumen 30 is smaller than the cross-sectional area of the first catheter lumen 28, and the further catheter lumen 30 is disposed in such a manner that it has a wall section 34 that is part of the tubular outer wall.

Regarding claim 3, wherein the partition 32 runs in arc shape over at least one section of same.

Regarding claim 4,wherein the arc-shaped partition 32 has a convex side that faces the first catheter lumen 28, and a concave side that faces the further catheter lumen 30.

Regarding claim 5 wherein the cross-sectional area of the first catheter lumen 28 has a rounded sickle shape.

Regarding claim 6, wherein the cross-sectional area of the further catheter lumen 30 is round.

Claims 1, 3, 6-8, 11-15 are alternatively rejected under 35 U.S.C. 102(e) as being anticipated by Currier et at. ('hereinafter 'Currier') (US 2004/0015138).

Currier discloses in Fig. 7 a catheter having a catheter body, the interior of which form a first catheter lumen 96, having at least one partition disposed in the interior, which divides off at least one further catheter lumen (94 or 98) in the interior, wherein the catheter body 88 has a tubular outer wall and the cross-sectional area of the further catheter lumen 94 or 98 is smaller than the cross-sectional area of the first catheter

lumen 96, and the further catheter lumen 94, 98 is disposed in such a manner that it has wall section that is part of the tubular outer wall. The partition runs in arc shape over at least one section (claim 3); the cross-sectional area of the further catheter lumen 94 or 98 is round (claim 6).

Regarding claims 7-8, Currier discloses a temperature sensor disposed in the vicinity of the catheter tip (para [0061]).

Regarding claim 11, an optical fiber sensor 102 is disposed in the further catheter lumen 98 (para [0058] and [0061]).

Regarding claim 12, the further catheter lumen 98 is open in the region of the catheter tip.

Regarding claim 13, the further catheter lumen 94 is closed in the region of the catheter tip.

Regarding claims 14-15, the catheter body is made of polyurethane plastic (para [0054]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beil as applied to claim 1 above, and further in view of Currier et al. (hereinafter 'Currier') (US 2004/0015138).

Beil teaches all the limitations of the claims except an optical fiber sensor disposed in the further catheter lumen, a temperature sensor disposed in the vicinity of the catheter tip. Currier discloses in Fig. 8A-B that a soft distal tip 110 includes a primary lumen 114 and a device lumen 116 that receives sensor. The sensors that can be used include fiber-optics, temperature sensor (see para [0061] or abstract).

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art use the optical fiber sensor and temperature sensor, as taught by Currier, apply in to Beil's device for the benefits of calibrating the fiber optics and measuring the temperatures within the patient's vascular system.

Regarding claims 9-10, Beil or Currier discloses the claimed invention except for the cross-sectional area of the temperature sensor fills the cross-sectional area of the further catheter lumen by at least four-fifths; wherein the cross sectional area of the temperature sensor fills the cross sectional area of the further catheter lumen completely. It would have been an obvious mater of design choice to make the size as forth-fifth or the temperature sensor filled in completely of cross sectional area of the catheter lumen, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Regarding claims 14-15, Beil does not discloses the catheter body is made of plastic having a Shore hardness of 60D to 85D, wherein the plastic is polyurethane. Currier discloses a catheter made of material less than or equal to 100 shore A hardness (para [0008]), the plastic is polyurethane (papa [0054]). Therefore, it would have been obvious at the time the invention was made of to a person having ordinary skill in the art to use the material as taught by Caurrier apply in Beil's device for sufficiently soft and flexible so as to deform or collapse when it encounters the inner wall of vessel or the heart wall. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for intended use as a matter of obvious design choice.

Regarding claim 16, Beil and Currier disclose the claimed invention except the guide wire has a diameter that amounts to 65% to 95% of the distance between the partition and the outer wall. It would have been obvious to one of ordinary skill in the art at the time the invention was made the diameter ranges from 65% to 95%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mooney et al (US 2002/0128568) disclose, in Fig. 11, a temperature sensor 120 is disposed at distal end.

Willis et al. (US 4,718,423) disclose a fiber optic sensor and a temperature sensor are disposed along the catheter (col. 3, lines 49-53), can apply for rejection of claims 1, 7-11.

Goble et al. (US 2004/0030281), Miraki (US 5,389,087) and Miller et al. (US 5,380,276) disclose all limitations of claims 1-6, 14-15.

Pfeiffer et al. (US 6,200,301) disclose the temperature sensor 3; a further catheter lumen 2 closed in the region of the catheter tip. It can be applied for rejection of claims 1, 7-8, 13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QNV

Matthew DeSmoto
5/14/07